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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,288	03/10/2004	Marlene M. Darfler	26204-002US	9373

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EXAMINER

PETERSEN, CLARK D

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/796,288

Applicant(s)

DARFLER ET AL.

Examiner

Clark D. Petersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 18-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment, filed 29 May 2007, in which claims 1, 5, and 6 were amended. Claims 1-39 have been presented for examination. This application contains claims 18-39 drawn to an invention nonelected **without** traverse in the reply filed on 14 Nov 2006. It is suggested that the reply to this office action include cancellation of nonelected claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All objections and rejections not repeated in the instant Action have been withdrawn due to Applicant's response to the previous Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (US 5,672,696, issued 30 Sept 1997, from IDS dated 29 May 2007).

Wang et al teach a method of treating paraffinized tissue samples to release analytes. In example 1, col. 9 line 53 to col. 10 line 21, Wang et al. add limonene to a slice of formaldehyde fixed and paraffin embedded human tissue to remove the paraffin, followed by mixing. The

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paraffin/limonene is removed and the sample is heated at 90 °C for 10 min, followed by adding papain protease. The sample is heated at 50 °C for 90 min. Both the heating and digestion samples contain SDS and Tris pH 7.0. The sample is then fractionated using isopropanol to precipitate recovered DNA. The supernatant after isopropanol treatment will still contain protein that would be suitable for analysis. Although Wang et al intend to analyze DNA, and *subsequently* discard the supernatant, the method they teach recites every step instantly claimed in claims 1-17. Therefore the teachings of Wang et al are deemed to anticipate instant claims 1-17.

Claims 1-4 and 7-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Banerjee et al (Biotechniques, 1995, from Applicants' IDS).

This rejection was previously presented in the Office Action mailed 27 February 2007 and is maintained for reasons of record and as set forth below.

Banerjee et al teach a method of retrieving useful analytes from paraffin-embedded tissue samples. They teach that one can make a lysate from serial sections from archived paraffin embedded blocks. Sections were placed in microfuge tubes and microwaved to separate the paraffin from the tissue section (see "Microwave Treatment", p. 770).

The tissue samples came from pancreatic and Syrian hamster kidney tissue, reading on instant claim 2 (see p. 772, col. 2). Once free of paraffin, samples were digested by Proteinase K overnight at 42 degrees C, or 3 hr at 55 degrees C, reading on instant claims 7, 8, and 13. Before heating the sample and removing paraffin, the authors crushed the tissue in a buffer comprising Tris pH 8.5, reading on instant claims 4 and 14. All steps, i.e. heating and protease digestion, are

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carried out in the presence of 0.5% Tween-20, reading on instant claims 9, 10 and 12 (see p. 770 col. 1; see “Microwave Treatment” and Proteinase Digestion and Analysis of DNA Samples”). They teach that the samples can be extracted with phenol/chloroform/isoamyl alcohol, which can separate cell lysates into various fractions that a skilled artisan knows can be used for various biochemical assays, for example a DNA pellet and protein fraction (see p. 772, col. 2).

Therefore the teachings of Banerjee are deemed to anticipate the instant claims 1-4 and 7-17.

Response to arguments - 35 USC § 112

Applicants traverse the rejection of claims 1, 5, and 6 in the Office Action mailed 27 February 2007 under 35 USC 112, second paragraph, as being indefinite. Based on Applicants’ amendment, this rejection is withdrawn.

Response to arguments - 35 USC § 102

Applicants traverse the rejection of claims 1-4 and 7-17 in the Office Action mailed 27 February 2007 under 35 USC 102(b) as being anticipated by Banerjee et al (Biotechniques, 1995, from Applicants’ IDS).

Applicants argue that Banerjee teaches only the extraction of DNA. For example Banerjee et al teaches the step of boiling the proteinase K-treated samples to denature residual protease and contaminating proteins, and that this step, for example, shows that Banerjee teaches away from preparing a lysate for any purpose other than DNA extraction.

These arguments have been carefully considered but are not deemed persuasive.

Banerjee teaches a method of treating a formalin-fixed paraffinized sample that is within the scope of the rejected claims, regardless of intended use. Banerjee's characterization of proteins as "contaminating" is not an objective description of a solution that is acknowledged to contain proteins. Inherently, because Banerjee describes all the method steps instantly claimed, these teachings must arrive at the instantly claimed invention. It is noted that in preparing a western blot, for example, protein samples are boiled before electrophoretic separation. Additionally, Banerjee et al teaches the centrifugation of the final product (see "Proteinase Digestion and Analysis of DNA Samples", pp. 770-772, for example), which is consistent with the Example provided in the instant Specification in which the final product is microcentrifuged (see p. 18, lines 13-23). Therefore, although Banerjee is concerned with analyzing DNA, these methods anticipate each and every step in the instant claims rejected.

Response to arguments - 35 USC § 103

Applicants traverse the rejection of claims 1-17 in the Office Action mailed 27 February 2007 under 35 USC 103(a) as being unpatentable over Banerjee et al in view of Ikeda et al (J Histochem Cytochem, 1998).

Applicants cite the recent KSR decision, and assert the need for an explicit analysis of the "apparent reason to combine the known elements in the fashion claimed by the patent at issue." Remarks filed 29 May 2007, at page 9. Ikeda teaches that one should deparaffinize samples before heating to release crosslinking, and that heating should occur within the scope recited in instant claims 5 and 6, for example. However Examiner acknowledges that it would be

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otherwise counterintuitive to one of ordinary skill in the art to subsequently proteolytically degrade a protein sample to be analyzed, as taught by Banerjee et al. Therefore it would not be obvious to one of ordinary skill in the art to combine the teachings of Banerjee et al with those of Ikeda et al.

Based on Applicants' arguments and the considerations above, this rejection is withdrawn.

Applicants traverse the rejection of claims 1-4 and 7-17 in the Office Action mailed 27 February 2007 under 35 USC 103(a) as being unpatentable over Banerjee et al in view of Kanai et al (Res Vet Sci, 1998). Based on Applicants' arguments, this rejection is withdrawn.

Applicants traverse the rejection of claims 1-4 and 7-17 in the Office Action mailed 27 February 2007 under 35 USC 103(a) as being unpatentable over Banerjee et al in view of Francis et al (Biochem J, 1980). Based on Applicants' arguments, this rejection is withdrawn.

Conclusion

No claims are allowed.

Because the new grounds of rejection were based on prior art in the Information Disclosure Statement provided by Applicants with claims amendments and remarks dated 29 May 2007, this Office Action is **FINAL**.

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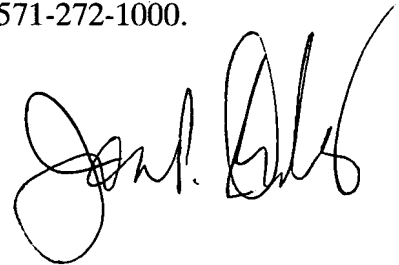
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358.

The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP 8/1/2007

A handwritten signature in black ink, appearing to read 'Jon Weber', with a stylized, cursive script.

Jon Weber
Supervisory Patent Examiner